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EXAMINER	
WOOLWINE, SAMUEL C	
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1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/743,991	CONNOLLY, D. MICHAEL	
	Examiner	Art Unit	
	SAMUEL C. WOOLWINE	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30,38,40 and 42-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30,38,40 and 42-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status

Applicant's response filed 07/13/2009 is acknowledged.

The double patenting rejections are withdrawn in view of the terminal disclaimer filed 07/13/2009.

The rejections under 35 USC 103(a) based on either of US 2003/0109031 or US 2003/0203384 are withdrawn in view of Applicant's declaration under 37 CFR 1.130 removing these references as prior art.

The rejections under 35 USC 103(a) based on US 2004/00686872 are withdrawn in view of Applicant's declaration under 37 CFR 1.131.

New rejections are set forth below. This Office action is NON-FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 10-19, 30, 38, 40, 42, 44, 45 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Butland et al (US 6,030,657, prior art of record) in view of Eichen et al (WO 99/57550, prior art of record), Besemer et al (US 6,114,122) and Liljestrand et al (US 2001/0008612).

With regard to claim 1, Butland taught nucleic acid taggants for preventing product diversion and counterfeiting (see entire document, especially abstract and

columns 3-5). In particular, the method comprises *recovering a nucleic acid containing taggant sample from an item, wherein the taggant sample potentially contains one or more target nucleic acids* (column 5, lines 1-5; column 6, lines 20-25).

With regard to claim 2, Butland taught adding "junk DNA" to the taggant (see column 8, line 58-64), which can be considered random nucleic acid molecules.

With regard to claim 3, Butland taught DNA molecules of 80-100 base pairs in length, which "comprises 10-30 nucleotides" (column 5, lines 60-61).

With regard to claim 4, Butland taught DNA and RNA (e.g. column 5-6; column 4, lines 66-67).

With regard to claim 7, Butland taught encapsulating the taggant in a matrix (e.g. casein; column 2, lines 47-54).

With regard to claim 13, Butland taught encapsulating the nucleic acid in a material that is resistant to the environment (column 2, lines 47-54), which would thus have resulted in a taggant that was stable under ambient conditions.

With regard to claim 14, Butland taught removal of the label for identification (column 4, line 66 through column 5, line 7).

With regard to claim 15, Butland taught ink (column 2, lines 47-54).

With regard to claim 16, Butland taught printing (i.e. labeling objects with an ink; column 1, line 64 through column 2, line 6).

With regard to claims 17-19, Butland taught removing the label from a shirt, which means the taggant sample was applied to a fabric. Butland then taught applying the taggant sample removed from the shirt to nylon. See column 5, lines 1-7.

With regard to claim 45, Butland taught that multiple different nucleic acids may be used (column 4, lines 6-30).

With regard to claim 1, Butland did not teach detection of the nucleic acid taggant by providing a detection unit comprising a plurality of reactant chambers and an insertable detection cartridge, wherein the insertable detection cartridge comprised at least one detection chamber, wherein the detection chamber comprised one or more sets of electrically separated electrical conductor pairs, each conductor having an attached capture probe such that a gap exists between the capture probes of a pair of electrically separated conductors, wherein the capture probes for each pair of electrically separated electrical conductors are complementary to one of the target nucleic acids.

Also with regard to claim 1, Butland did not teach storing reactants in the plurality of reactant chambers, introducing the recovered taggant sample into the detection unit, transferring the recovered taggant sample into the detection chamber, or transferring reactants from the plurality of reactant chambers into the detection chamber to contact the sample with the reactants and establish conditions effective to permit any target nucleic acid present in the taggant sample to bind to the capture probes, thereby connecting the capture probes.

Finally with regard to claim 1, Butland did not teach detecting any target nucleic acid present in the taggant sample by determining whether electricity is conducted between the electrically separated conductors, thereby identifying the tagged item.

With regard to claim 5, Butland did not teach capture probes comprising 10-30 nucleotides.

With regard to claim 6, Butland did not teach capture probes of DNA, RNA, peptide nucleic acids or locked nucleic acids.

With regard to claim 10, Butland did not teach contacting the capture probes with ligase and heating the capture probes to a temperature high enough to denature any non-ligated target nucleic acids from the capture probes.

With regard to claims 11 and 12, Butland did not teach applying a conductive material over the capture probes and any target nucleic acid, or that the conductive material was selected from gold, silver and mixtures thereof.

With regard to claims 30 and 45, Butland did not teach a plurality of pairs of separated electrical conductors, each specific for a different target nucleic acid or the simultaneous detection of each target nucleic acid in the taggant sample.

With regard to claim 38, Butland did not teach a waste chamber.

With regard to claim 40, Butland did not teach that the introducing the sample into the detection unit and detecting the target nucleic acid took place in fifteen to thirty minutes.

With regard to claim 42, Butland did not teach pumping reactants.

With regard to claim 44, Butland did not teach "programming" the detection unit to transfer the reactants.

With regard to claim 47, Butland did not teach that the detection unit was portable.

Hence, the difference between Butland and the claimed invention is the manner in which the nucleic acid in the taggant is detected.

With regard to claim 1, Eichen taught *one or more sets of electrically separated electrical conductor pairs* (electrical conductor = electrode; see e.g. page 12, line 15 through page 13, line 6; page 29, lines 20-24, and figure 10)*, each conductor having an attached capture probe such that a gap exists between the capture probes of a pair of electrically separated conductors* (capture probe = recognition moiety; see e.g. page 12, line 15 through page 13, line 6; page 29, lines 20-24, and figure 10)*, wherein the capture probes for each pair of separated electrical conductors are complementary to one of the target nucleic acids* (see page 11, lines 3-5, page 29, lines 20-24, and figure 10)*; contact[ing] the sample with the reactants* (see e.g. page 12, line 15 through page 13, line 6; page 29, lines 20-24, and figure 10) *and establish[ing] conditions effective to permit any target nucleic acid present in the … sample to bind to the capture probes, thereby connecting the capture probes* (see e.g. page 12, line 15 through page 13, line 6; page 29, lines 20-24, and figure 10)*; and detecting any target nucleic acid present in the … sample by determining whether electricity is conducted between the electrically separated conductors* (see e.g. page 12, line 15 through page 13, line 6; page 29, lines 20-24, and figure 10).

With regard to claim 5, Eichen taught capture probes of 12 nucleotides each (see page 41, line 18 through page 42, line 11).

With regard to claim 6, Eichen taught capture probes which are nucleic acids in general (page 11, lines 3-5) and DNA in particular (e.g. page 11, lines 6-7; page 35, lines 10-19). Eichen also implicitly taught RNA (statement spanning pages 59-60).

With regard to claim 10, Eichen taught ligation (page 30, lines 20-23) and taught washing at elevated temperatures to remove unbound nucleic acids and ensure high selectivity in duplex formation (page 31, lines 1-4; page 46, lines 28-30; page 55, lines 10-14).

With regard to claim 11, Eichen taught applying a conductive material over the complex formed by the capture probes and target nucleic acid (page 8, lines 17-20; page 29, lines 20-24, and figure 10).

With regard to claim 12, Eichen taught gold and silver (page 29, lines 20-24, and figure 10).

With regard to claims 30 and 45, Eichen taught a device having a plurality of sites for detecting different targets (see page 19, lines 11-22). Even if the term multiplexing did not imply simultaneous detection (which it does), it would have been obvious to detect these different targets simultaneously as recited in claim 45 in order to save time.

With regard to claim 1, Besemer taught an apparatus with "a fluid delivery system for delivering and injecting selected fluids into an array cartridge or package which includes a hybridization chamber having a polymer array incorporated therein" (column 2, lines 20-25). Besemer also taught that the apparatus included "a mounting system

for holding the hybridization chamber within the array cartridge in fluid communication with the fluid delivery system" (column 2, lines 25-30).

Besemer taught the apparatus could be referred to as a "fluidics station" or "hybridization station", since it was used in conducting hybridization reactions (column 3, lines 15-18). Besemer taught the station was used to deliver a sample or wash solution (column 3, lines 20-21) as well as buffer (column 5, lines 45-50) to a hybridization reaction chamber.

Besemer taught the array cartridges comprised an array packaged within a housing in such a way as to define a reaction cavity (i.e. a "detection chamber"; see column 3, line 65 through column 4, line 10). Besemer taught the array cartridge was to be inserted in the assembly devices, fluidics stations and reader devices (column 4, lines 20-23; see also column 10, lines 30-32 and figure 3A and B). Hence, Besemer clearly taught an "insertable detection cartridge" comprising a "detection chamber" to be used with a fluidics/hybridization station ("detection unit") for transferring sample and reactants (e.g. "wash solution", "buffer") into the "detection chamber". The fluidics/hybridization station ("detection unit") comprised a "plurality of reactant chambers" (see column 6, lines 3-11: "reagent vessels **202, 216-220**" and see figure 2).

Besemer also taught introduction of a sample into the detection unit. See column 6, line 28: "For example, when a sample is to be injected into the hybridization chamber/array cartridge **100**, the valve assembly **208** is opened to provide a fluid connection between pump **206** and sample vessel **202**, via sample tube **204**." See also figure 2.

With regard to claim 38, Besemer taught a waste chamber (column 6, lines 14-18 and see figure 2; see also column 7, lines 28-31).

With regard to claim 42, Besemer taught pumping the reactants (column 6, lines 3-23 and see figure 2; see also column 7, lines 18-21).

With regard to claim 44, Besemer taught (column 3, lines 18-27) "a fluid delivery system…and a process control system for operating each of these individual systems according to preprogrammed operating profile." See also column 12, lines 32-45.

The only remaining difference between the claim 1 and the teachings of Butland, Eichen and Besemer is that claim 1 recites a "detection unit" and the final step of "detecting". Besemer did not teach detection within the array cartridge while it was in the "fluidics station" or "hybridization station" (which station the examiner has likened to the claimed "detection unit" in that it receives the "insertable detection cartridge" (i.e. the array cartridge of Besemer) and serves to transport sample and reagents into the "detection chamber" of the "insertable detection cartridge". Besemer taught that, following hybridization and washing, the array cartridge was transferred to a "reader/scanner device" for detection (column 28, lines 12-18). It is noted that Besemer taught typically the samples being analyzed included target nucleic acid that incorporated a fluorescent or gold label for subsequent detection. That is, Besemer was teaching an optical detection format, which would have thus required optical detection equipment.

However, Liljestrand taught insertable detection cartridges comprising electrodes, which insertable detection cartridges were inserted into an apparatus that

introduced both sample and reagent, as well as provided for detection in the same apparatus (figure 7 and paragraph [0135]; figure 8 and paragraph [0155]).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the technology of Eichen to detect the target nucleic acids in the taggant sample when practicing the method of Butland. One would have been motivated to do so because Eichen taught at the bottom of page 11 that his method was “highly sensitive, allowing the formation of a conductive bridge even where few, or even a single complex between a recognition moiety and a target is formed between, or on the electrodes of an assay set.” Additionally, it would have been *prima facie* obvious to place the electrode pairs within an insertable cassette and carry out the hybridization in a system such as disclosed by Besemer, since Besemer's system provided for "rapidly and efficiently carrying out repeated hybridizations" (column 2, lines 18-21) and for automation (column 12, lines 33-36). Moreover, since Eichen's technology involved the formation of silver-coated connections between the electrode pairs (page 29, lines 20-24, and figure 10), it would have been obvious to use the insertable cassette format of Besemer, since one of skill in the art would have realized that to re-use the electrodes (if this were even possible), the silver or gold deposits would need to be removed. By employing the insertable cassette format, another assay could be conducted using a second cassette while the first cassette was reconditioned, thereby increasing assay throughput. It would also have been obvious to integrate both fluid transport functions and detection functions into a single apparatus ("detection unit") into which the insertable cassette was inserted, since Liljestrand demonstrated this was

known and well within the skill of the art. Although Besemer and Liljestrand taught different detection technologies than Eichen (i.e. optical detection and electrochemiluminescent detection, respectively, vs. conductive bridge formation), the references are relied upon to demonstrate that it was known in the art to use insertable cartridges in conjunction with an apparatus providing fluid transport and detection.

With regard to claim 40, if it is Applicant's intent that the claimed invention is *capable* of providing for detection within 30 minutes, this is considered a recitation of an inherent property of the method. As discussed in MPEP 2112.01(I), when the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent. In this instance, since the prior art suggests the claimed method as well as the materials and structures used in its practice, the *ability* of the method suggested by the combined teachings of the references to achieve detection within 30 minutes is presumed inherent. If, however, the limitations of claim 40 refer to an arbitrarily chosen time between introduction of the sample and the detection step, it would have been well within the skill of the ordinary artisan to determine the appropriate incubation/reaction time of the assay.

With regard to claim 47, see MPEP 2144.04(V): "Fact that a claimed device is portable or movable is not sufficient by itself to patentably distinguish over an otherwise old device unless there are new or unexpected results." Furthermore, the advantage of portability was well-recognized across diverse fields of technology.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Butland et al (US 6,030,657, prior art of record) in view of Eichen et al (WO 99/57550, prior art of record), Besemer et al (US 6,114,122) and Liljestrand et al (US 2001/0008612) as applied to claims 1-7, 10-19, 30, 38, 40, 42, 44, 45 and 47 above and further in view of Stone (USPN 5,512,436, prior art of record) and McMahon et al (USPN 5,310,650, prior art of record).

The teachings of Butland, Eichen, Besemer and Liljestrand have been discussed. Furthermore, Eichen taught addition of Denhardt's solution to the sample containing the DNA to be detected (page 54, lines 28-30).

Butland, Eichen, Besemer and Liljestrand did not teach selecting a matrix material from the group consisting of the recited compounds.

As evidenced by McMahon et al (column 9, lines 50-55), Denhardt's solution contains polyvinyl pyrrolidone and was a preferred blocking agent for hybridization assays. Stone taught that polyethylene glycol and polyvinyl alcohol were notable examples of hybridization rate enhancers (column 3, lines 30-33).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention of the instant application was made to include compounds such as polyvinyl pyrrolidone, polyethylene glycol or polyvinyl alcohol in the matrix containing the nucleic acid taggant since these compounds were known in the art to enhance nucleic acid hybridization, which was a critical component of the detection method taught by Eichen.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Butland et al (US 6,030,657, prior art of record) in view of Eichen et al (WO 99/57550, prior art of record), Besemer et al (US 6,114,122) and Liljestrand et al (US 2001/0008612) as applied to claims 1-7, 10-19, 30, 38, 40, 42, 44, 45 and 47 above and further in view of Connolly (USPN 6,248,529 B1, prior art of record).

The teachings of Butland, Eichen, Besemer and Liljestrand have been discussed.

Butland, Eichen, Besemer and Liljestrand did not teach contacting the capture probes with nucleases.

Eichen's method was based on hybridizing a target nucleic acid to two capture probes, thus providing a continuous filament upon which a conductive metal is deposited so as to establish an electrical circuit connecting two electrodes (see rejection of claim 1 above).

Connolly taught methods for using nucleic acids to form a circuit by depositing, for example, metals thereon: "The negatively charged backbone of a nucleic acid molecule can be used to attract and attach materials necessary to form circuit elements. Metals, doped metals, and other materials can be specifically bound to exposed regions of a DNA molecule" (column 11, lines 16-20).

Connolly also taught: "The method of manufacturing a circuit element may further consist of disrupting or removing the DNA template from the circuit or a portion thereof. Nucleic acid molecules have intrinsic electric properties, which may interfere with the functioning of certain circuit elements. One may take into account the electrical properties of the nucleic acid molecule in the design of the element. Where it is not

possible to incorporate the intrinsic properties of the nucleic acid molecule into the circuit element, it may be preferred to disrupt or remove the nucleic acid molecule or a portion of the molecule" (column 3, lines 57-67, emphasis provided).

Finally, Connolly taught: "Once a material is deposited on the nucleic acid molecule, the nucleic acid molecule can be disrupted and/or removed by using treatments which will specifically disrupt the nucleic acid molecule but not affect the circuit elements. Nucleic acid molecules can be disrupted, or possibly removed, by treating the circuit with nucleases, ionizing radiation, oxidizing compounds" (column 13, lines 5-11).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the method taught by the combined teachings of Butland, Eichen, Besemer and Liljestrand to add a step of nuclease treatment after the metal deposition (and hence, after the “contacting” step), in order to remove the nucleic acid because Connolly taught that nucleic acids have intrinsic electrical properties that may interfere with the functioning of circuits made in this manner.

Claims 20, 21, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Butland et al (US 6,030,657, prior art of record) in view of Eichen et al (WO 99/57550, prior art of record), Besemer et al (US 6,114,122) and Liljestrand et al (US 2001/0008612) as applied to claims 1-7, 10-19, 30, 38, 40, 42, 44, 45 and 47 above and further in view of Bancroft et al (US 6,312,911, prior art of record).

The teachings of Butland, Eichen, Besemer and Liljestrand have been discussed.

Butland, Eichen, Besemer and Liljestrand did not teach that the tagged item is a paper or plastic, or more specifically a paper or plastic label. Nor did these references teach applying the taggant to a medicament (or a capsule, pill, tablet, lozenge or ointment).

Bancroft taught a method of authenticating an object by tagging it with a hidden DNA (see, for example, abstract and column 1, lines 8-15). The method includes *recovering a nucleic acid containing taggant sample from an item, wherein the taggant sample potentially contains one or more target nucleic acids* (e.g. column 12, lines 2-5).

Bancroft taught applying the taggant to tags made of paper, plastic, nitrocellulose, nylon or fabric (column 7, lines 23-27). Bancroft taught using the DNA taggant to authenticate pharmaceuticals in either liquid or solid forms (column 10, lines 20-25).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the method suggested by the combined teachings of Butland, Eichen, Besemer and Liljestrand by applying the taggants to tags made of paper or plastic as suggested by Bancroft, since the principle idea is the same in both Butland and Bancroft. Hence, paper or plastic tags were merely obvious items to which to apply the taggants. Furthermore, and for the same reason, it would have been obvious to apply the taggant to pharmaceuticals in either liquid or solid form as taught by Bancroft, and pills, tablets or lozenges would have been obvious "solid forms" of pharmaceuticals.

Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Butland et al (US 6,030,657, prior art of record) in view of Eichen et al (WO 99/57550, prior art of record), Besemer et al (US 6,114,122), Liljestrand et al (US 2001/0008612) and Bancroft et al (US 6,312,911, prior art of record) as applied to claims 20 and 21 above and further in view of Ryan (USPN 5,982,282, prior art of record).

The teachings of Butland, Eichen, Besemer, Liljestrand and Bancroft have been discussed.

These references did not say anything about the label being tamper proof.

Ryan taught a tamper proof device (i.e. a label) for verifying the authenticity of merchandise (see column 1, lines 5-10 and figure 1). Ryan taught the housing of the device was molded plastic (column 2, lines 44-45). Ryan taught the device contained a bar-code (i.e. it is a bar-code label; column 3, lines 3-13). Ryan taught the device contained an authentication element such as DNA (column 4, lines 39-41). Ryan taught the device was tamper proof (column 3, lines 54-64).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention of the instant application was made to use a tamper proof barcode label comprising DNA as taught by Ryan in the method of verifying authenticity of an item using a DNA taggant as suggested by the combination of Butland, Eichen, Besemer, Liljestrand and Bancroft. One would have been motivated to use a tamper proof device as taught by Ryan in order to prevent a counterfeiter or other malefactor from altering or discovering the DNA taggant.

Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Butland et al (US 6,030,657, prior art of record) in view of Eichen et al (WO 99/57550, prior art of record), Besemer et al (US 6,114,122) and Liljestrand et al (US 2001/0008612) as applied to claims 1-7, 10-19, 30, 38, 40, 42, 44, 45 and 47 above and further in view of Benardelli (USPN 5,020,831, prior art of record).

The teachings of Butland, Eichen, Besemer and Liljestrand have been discussed. These references did not teach using the DNA taggant on cardboard packaging containing the item to be identified.

Benardelli taught a method of tagging an item with a latent label for purposes such as certification and prevention of counterfeiting (see claim 1). Benardelli taught applying the tag to packaging (see claim 1). Benardelli taught the package could be cardboard (column 7, lines 9-13 and figure 6; column 4, line 64 through column 5, line 2).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention of the instant application was made to apply the DNA taggant taught by Butland to cardboard packaging containing the item to be identified, since Benardelli demonstrated that cardboard packaging was known in the art as a location for latent indicia for purposes of authentication and counterfeit-prevention, which was the precise purpose of the DNA taggants taught by Butland (see entire document, especially abstract and columns 3-5).

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Butland et al (US 6,030,657, prior art of record) in view of Eichen et al (WO 99/57550, prior art of record), Besemer et al (US 6,114,122) and Liljestrand et al (US 2001/0008612) as applied to claims 1-7, 10-19, 30, 38, 40, 42, 44, 45 and 47 above and further in view of Heller et al (USPN 5,849,486, prior art of record).

The teachings of Butland, Eichen, Besemer and Liljestrand have been discussed. These references did not teach displaying the results of the step of identification. Besemer discusses displaying conditions of the hybridization or the status of a given protocol on an LCD (column 12, lines 14-18), but not specifically the results of the detection.

Heller taught displaying results to a user on a monitor (column 7, lines 14-15).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to display the results of detection, since this was common in the art as disclosed by Heller. In addition, since Eichen's technology for detection was based on electrical conductivity, and since one cannot "see" this directly, one of skill would have known that the results of detection would have to be displayed in some fashion in order for the results to be observed.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Butland et al (US 6,030,657, prior art of record) in view of Eichen et al (WO 99/57550, prior art of record), Besemer et al (US 6,114,122) and Liljestrand et al (US 2001/0008612) as

applied to claims 1-7, 10-19, 30, 38, 40, 42, 44, 45 and 47 above and further in view of Laska et al (US 2002/0045243).

The teachings of Butland, Eichen, Besemer and Liljestrand have been discussed. These references did not teach and insertable detection cartridge containing a plurality of reactant chambers. In Besemer, the plurality of reactant chambers was external to the insertable detection cartridges.

Laska taught "cartridges, analytical instrument systems and methods for simple, safe and efficient handling and analysis of a sample" (paragraph [0005]). Laska taught (paragraph [0027]): "Cartridges of the invention can be disposable or reusable and are typically constructed for fluid flow into, out of, and internally throughout the cartridge. The cartridges can be manually operated or used with an analytical instrument and configured to interface with the instrument and present the sample at a location and in a form appropriate for analysis of the sample by the instrument." Laska taught the cartridge could be inserted into an analytical instrument (paragraph [0038]).

Laska taught (paragraph [0039]): "In most embodiments a cartridge will contain all reagents or other components necessary to perform a single or multiple analyses. Thus, various cartridges containing the reagents or other components necessary to perform a particular analysis, will be available. Alternatively, the cartridge may contain some or none of the necessary reagents for an analysis. In this case, the sample or fluid necessary for a particular analysis can be introduced into the cartridge by the instrument or a human as needed."

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the method suggested by the combined teachings of Butland, Eichen, Besemer and Liljestrand by incorporating the reagent reservoirs into the insertable detection cartridge as taught by Laska, because Laska taught (pararaph [0038]): "because all samples can be processed entirely within the cartridge, no sample, reagent or other component is introduced into the instrument thus reducing the possibility of instrument or cross sample contamination."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAMUEL C. WOOLWINE whose telephone number is (571)272-1144. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel Woolwine/
Examiner, Art Unit 1637